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EXAMINER

HM12/0731

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ART UNIT	PAPER NUMBER
1644	10
1644	

DATE MAILED: 07/31/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 5/18/00 ☑ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 8-13, 15-28 are pending in the application.
   Of the above, claims 12, 13, 23-25 are withdrawn from consideration.
2. ☑ Claims 1-7, 14 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 8-11, 16-22, 26-28 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

DETAILED ACTION

1. Applicant's amendment, filed 5/18/00 (Paper No. 9), is acknowledged.
Claims 9-11 have been amended.
Claims 15-28 have been added.

Claims 1-7 and 14 have been canceled previously.

Claims 8-13 and 15-28 are pending.

Applicant's election with traverse of Group II and the species CD40 binding protein as it read on CD40 ligand in Paper No. 6 is acknowledged.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Claims 12-13 and newly added claims 23-25 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention and species.

Claims 8-11, 16-22 and 26-28 as they read on dendritic cells contact with CD40L/CD40-specific antibody are under consideration in the instant application.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 5/18/00 (Paper No. 9).
The rejections of record can be found in the previous Office Action (Paper No. 8).

3. Applicant is reminded to amend the first line of the specification to update the status of the priority documents. USSNs 08/725,540 and 08/5390,142 are now abandoned.

4. Applicant is reminded that the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. Applicant's amended claims, filed 5/18/00 (Paper No. 9), have obviated the previous rejection under 35 U.S.C. 112, first paragraph,

6. Newly added claims 26-28 are objected to because "CD40 ligand" is the proper designation of this molecule and not "CD-40 ligand".

7. Claims 8-11 and newly added claims 15-22 and 26-28 are rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Steinman et al. (U.S. Patent No. 5,851,756) for the reasons of record set forth in Paper No. 9.

Applicant's arguments, filed 5/18/00 (Paper No. 9), have been fully considered but are not found convincing.

Applicant argues in conjunction with Pulendran et al. (PNAS 96: 1036-1041, 1999; Exhibit A) and Brasel et al. (Exhibit B) that culturing dendritic cell populations with different cytokines leads to distinct dendritic cell subsets.

Applicant states that the culturing with GM-CSF is a crucial aspect of the prior art reference Steinman et al.

Applicant argues that Steinman et al. does not teach the use of flt-3- ligand, which leads to dendritic cell populations expressing phenotypes of both lymphoid-type and myeloid-type dendritic cell populations.

Therefore, applicant argues that the prior art results in a dendritic cell populations with a myeloid-flavor.

However, as applicant acknowledges Steinman et al. teaches the use of GM-CSF in combination with additional cytokines in addition to GM-CSF (e.g., see column 14, paragraph 4).

While applicant focuses on the use of GM-CSF alone, the prior art teaches a combination of cytokines including GM-CSF.

Further it is noted that the claimed dendritic cell populations are product-by-process claims which recite "comprising" with "one or more cytokines". which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03

Again, Steinman et al. teach dendritic cell populations including antigen pulsed and transfected cell populations as well as their expansion by a number of cytokines (see entire document, including Summary of the Invention; Detailed Description of the Invention, columns 18-23).

The recitation of a process limitation in the instant claims is not seen as further limiting the claimed product, as it is presumed that equivalent products can be obtained by multiple routes The patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

While it is acknowledged that Steinman et al. differs from the claimed invention by not disclosing flt3-ligand and CD40 binding proteins per se in expanding dendritic cell populations.

Although the elected species are flt3-ligand and CD40L/CD40-specific antibodies; applicant has not provided objective evidence that given the combination of cytokines taught in the prior art would not result in dendritic populations having both lymphoid and myeloid related dendritic cells.

Applicant arguments have not been found persuasive.

8. Claims 8-11 and newly added claims 15-22 and 26-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinman et al. (U.S. Patent No. 5,851,756) in view of
Lyman et al. (U.S. Patent No. 5,554,512; 1449) AND Inaba et al. (PNAS 90: 3038-3042, 1993) AND/OR in further view of
Gruss et al. (Blood 84: 2305-2314, 1994) AND/OR Caux et al. (Research in Immunology 145: 235-239, 1994) for the reasons of record set forth in Paper No. 9

Applicant's arguments, filed 5/18/00 (Paper No. 9), have been fully considered but are not found convincing.

Applicant argues in conjunction with In re Vaeck and In re Dow Chemical Co. That the claimed invention is not taught or suggested in the prior art and no motivation is provided in the prior art to use flt3-ligand to make dendritic cells.

Applicant argues that generating dendritic cell populations are different in kind from those generated with only GM-CSF possess distinct and unexpected properties or advantages over GM-CSF generated dendritic cell populations of Steinman; that is, flt3-ligand generates dendritic cell populations have significant numbers of both myeloid-like and lymphoid-like dendritic cells.

Applicant argues that none of the references teach the use of flt3-ligand to generate dendritic cells as opposed to a variety of other hemopoietic cells.

Applicant argues that the secondary references do not cure the deficiencies of the primary references, since they do not teach contacting hemopoietic cells with flt3-ligand.

Applicant assets that given the rarity of dendritic cells, Steinman implies the opposite conclusion of stimulating dendritic cells with GM-CSF, which leads to a population of dendritic cell population which is different from that generated by flt3-ligand.

In contrast to applicant's assertions, the claims encompass a preparation of dendritic cells, including contacting hemopoietic stem or progenitor cells with flt3-ligand and CD40L/CD40-specific antibodies and encompassing stimulation with one or more cytokines.

Even though the claimed dendritic cell populations are stimulated flt3-ligand and CD40L/CD40-specific antibodies; the claimed dendritic cell populations encompass hemopoietic cell populations stimulated with cytokines resulting in dendritic cell populations.

However, as applicant acknowledges Steinman et al. teaches the use of GM-CSF in combination with additional cytokines in addition to GM-CSF (e.g., see column 14, paragraph 4).

While applicant focuses on the use of GM-CSF alone, the prior art teaches a combination of cytokines including GM-CSF.

Further it is noted that the claimed dendritic cell populations are product-by-process claims which recite "comprising" with "one or more cytokines". which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03

Again, Steinman et al. teach dendritic cell populations including antigen pulsed and transfected cell populations as well as their expansion by a number of cytokines (see entire document, including Summary of the Invention; Detailed Description of the Invention, columns 18-23).

Again, Lyman et al. teach the use of flt3-ligand alone in combination with other cytokines encompassed by the claimed invention to stimulate the proliferation of hemopoietic and non-hemopoietic stem cells (see entire document, columns 6-7).

As pointed out previously, Inaba et al. teach the granulocytes, macrophages and dendritic cells arise from a common hemopoietic progenitor, wherein said progenitor are stimulated by cytokines such as GM-CSF (see entire document, including Abstract, Introduction). Given that dendritic cells have a common stem cell with other hemopoietic progenitors/stem cells and the cytokines such as GM-CSF provided stimulatory activity to such stem/dendritic cells; the provision of flt3-ligand and GM-CSF would have been expected to provide stimulatory activity of various hemopoietic cells, including dendritic cells at the time the invention was made.

With respect to stimulating dendritic cell populations via CD40/CD40L; both Gruss et al. And Caux et al. teach that antigen presenting cells, including dendritic cells, are conducive to CD40-dependent activation as well as other cytokines.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine various cytokines to stimulate dendritic cell populations, including antigen-representing dendritic cell populations of interest.

It is noted that the claimed dendritic cell populations are product-by-process claims which recite "comprising" with "one or more cytokines". which leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03.

Although the elected species are flt3-ligand and CD40L/CD40-specific antibodies; applicant has not provided objective evidence that given the combination of cytokines in stimulating hemopoietic cells including dendritic cells, including the use of flt3-ligand and CD40L/CD40-specific antibodies in combination with other cytokines, including GM-CSF, taught in the prior art would not result in dendritic populations having both lymphoid and myeloid related dendritic cells, encompassed by the claimed dendritic cell populations.

Also, it is noted that the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144.

While applicant appears to focus on the advantages of dendritic cell populations stimulated with flt3-ligand only resulting in a population with lymphoid-related/myeloid-related dendritic cells; stimulating hemopoietic cells or dendritic cells with the prior art cytokines, including flt3-ligand and CD40L/CD40-specific antibodies, would have resulted in dendritic cell populations encompassed by the claimed invention, including dendritic cell populations which comprise lymphoid-related/myeloid-related dendritic cells.

In contrast to applicant's assertions, there was sufficient motivation and expectation of success in stimulating hemopoietic cells or dendritic cells with the prior art cytokines, including flt3-ligand and CD40L/CD40-specific antibodies; which, in turn, would have resulted in dendritic cell populations encompassed by the claimed invention, including dendritic cell populations which comprise lymphoid-related/myeloid-related dendritic cells.

Applicant's arguments are not found persuasive.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
July 31, 2000